

FRANCIS J. PIZZI, M.D.
FELLOW AMERICAN COLLEGE OF SURGEONS
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ANTHONY A. CHIURCOM D.
FELLOW AMERICAN COLLEGE OF SURGEONS
DIPLOMATE AMERICAN BOARD OF
NEUROLOGICAL SURGEONS

NEURO-GROUP, P.A.

8 QUAKERBRIDGE PLAZA
TRENTON, N.J. 08619
(609) 890-0345
FAX # (609) 584-0430
(1-800) 449-3472

NEUROLOGICAL SURGERY

12/6/99

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

To Whom It May Concern:

I am deeply concerned about the proposed FDA regulation regarding **allograft** tissue which is used in daily surgery.

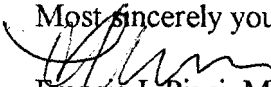
As a practicing neurosurgeon for thirty years I have been using **allograft** bone to perform anterior cervical microdiscectomies and fusions for over twelve years. To date there have been absolutely no complications with the use of this tissue, no rejections, and a 100% fusion rate. Prior to this we would use **autograft** taken from the patient's hip, which procedure was far more uncomfortable than the actual operation. This, to me, represents a great advance in the practice of neurosurgery in that pain and suffering is alleviated from an appropriate operation and iatrogenic pain and suffering from **graft** harvesting has been eliminated.

I am deeply concerned that the proposed legislation may lead to a curtailed supply of bone products and thus result in a denial of care to patients who require this procedure. My use of **allograft** bone tissue for these procedures is in excess of 100 grafts per year.

Our patients have enough trouble dealing with the HMO's who are constantly denying care to them for pecuniary reasons. This regulation will further add to their frustration should the supply of **allograft** banked bone become curtailed.

Thank you for listening to my comments. Should you require any further information or in fact oral testimony in Washington, I would be happy to do so.

Most sincerely yours,


Francis J. Pizzi, M.D.
Chairman, Dept. of Neurosurgery
St. Francis Medical Center
Trenton, NJ

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O-GROUP, P.A.
CERBRIDGE PLAZA
NTON, N.J. 08619

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